



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/670,568 | 01/18/2001 | Yoji Ikawa | Q61014 | 5597 |

7590

07/14/2003

Sughrue Mion Zinn
Macpeak & Seas
2100 Pennsylvania Avenue NW
Washington, DC 20037-3202

EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/670,568

Applicant(s)

IKAWA ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,6,7,16,17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7,16,17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 11 May 2001 is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Sequence alignment*.

Art Unit: 1642

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Misook Yu.

DETAILED ACTION

Claims 1-3, 6, 7, 16, 17, and 19-22 are pending and examined on merits.

Applicant states in the amendment (Paper No. 21) filed on 6-12-2002 that the Office failed to set forth the status of claims 17 and 22. The prosecution history indicates that claims 17 and 22 were indicated as allowable in the previous Office action.

Oath/Declaration

Receipt of the substitute Declaration filed on 6-12-2002 is acknowledged. However, the substitute Declaration says applicant claims foreign priority to PCT/JP99/01512, which is inconsistent with applicant's petition to change the status of the instant application to 371, a national stage of the PCT application. As discussed with Mr. Drew Hissong over the phone on 7/9/2003, a substitute Declaration saying that the application was filed on 3/24/1999 as PCT International Application Number PCT/JP99/01512 would correct the defect in the substitute Declaration .

Drawings

The corrected or substitute drawings were received on 5-11-2001. These drawings are acceptable.

Claim Rejections - 35 USC § 112

Rejection of claims 6 and 7 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

Rejection of claim 2 under 35 U.S.C. 102(b) as being b by Fu et al (Proc. Natl. Acad. Sci. vol. 92, pages 10162-6) is withdrawn because claim 2 is interpreted as drawn to isolated DNA molecule encoding a protein with the recited function and the art of record does not disclose DNA sequence that meets the limitation of the claim i.e., DNA encoding a protein with the recited functions.

Rejection of claims 6 and 7 under 35 U.S.C. 102(b) as being b by Fu et al (Proc. Natl. Acad. Sci. vol. 92, pages 10162-6) is withdrawn because the art of record says that at least 5 bases have to be matched in order to hybridizes to a DNA molecule to be sequenced. However, the sequences disclosed in the art of record does not appear to have at least 5 identical nucleotide in instant SEQ ID NO:1.

Allowable Subject Matter

The indicated allowability of claims 1, 3, and 16-22 is withdrawn in view of the newly discovered reference(s) to GenEmbl accession number Y11414 and Chan et al (1993, Proc. Natl. Acad. Sci. USA. vol. 90, pages 11371-5). These claims are subjected to new grounds of rejection under 102, see below.

Rejections based on the newly cited reference(s) follow.

NEW GROUNDS OF REJECTION

Sequence Rules

This application contains, for example at pages 116, 122, Figs. 2 and 3, Figs 12-15, sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this

Art Unit: 1642

application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. 37 CFR 1.821(a) presents a definition for "nucleotide and/or amino acid sequences." The instant application contains an unbranched specifically defined sequence of more than ten nucleotides at pages 12, 13 and 15. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422). Identifying each sequence at page 122, Figs. 2, 3, and 12-15 with unique SEQ ID NOs would satisfy this requirement.

Claim Rejections - 35 USC § 112

Claims 2, 3, 6, 7, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 6, and 7 recites "under stringent conditions" but it is not clear what the metes and bounds.

Claim Rejections - 35 USC § 102

Claims 1, 2, 6, 7, 16, 17, 19, and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by GenEmbl accession number Y11414 (Sep. 02, 1997) as evidenced by Kaghad et al (IDS, Cell vol. 90, pages 809-19).

In part (b) of claims 1, 20, and 21, the proviso "said protein contains a deletion, substitution, or addition of one **or more** amino acids" opens the claims up to any number of changes in the protein sequence. Therefore, claims 1, 20, and 21 read upon any isolated DNA molecule encoding any protein with transcriptional control activity or growth inhibition activity or apoptosis induction activity. Since the specification does not specify "stringent hybridization conditions", claims 2, 6, 7 read on any DNA molecule with about 15 nucleotides match to instant SEQ ID NO:2 and encodes a protein with transcriptional activity, growth inhibition, or apoptosis induction.

GenEmbl accession number Y11414 teaches a nucleic acid encoding p73beta protein (Kaghad et al teach at page 819 last sentence that the DNA encoding p73beta protein is deposited in EMBL data base with the accession number Y11414). Kaghad et al teach at page 813, right column that the p73beta protein has transcriptional activity and growth suppression activity, which contains deletion, addition, and/or substitution of more than one amino acid. See the attached alignment. The DNA stretches of Y11414 with 100 % match will hybridize to the DNA molecule encoding instant SEQ ID NO:1 under any hybridizing conditions. Thus, instant claims 1, 2, 6, 7, 16, 17, 19, and 20-22

read on the DNA molecule with GenEmbl accession number Y11414. The functional activity recited in the instant claims is the inherent characteristics of the protein encoded by GenEmbl accession number Y11414. This rejection affects all dependent claims.

Claims 1, 16, 17, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Chan et al (1993, Proc. Natl. Acad. Sci. USA. vol. 90, pages 11371-5).

The claims as written read on any DNA molecule encoding a transcription factor because the claimed DNA molecule does not necessarily encode a protein with common molecular structure to SEQ ID NO:1. Chan et al teach DNA encoding a transcription factor. See Fig. 1 and 5. This rejection affects all dependent claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/670,568
Art Unit: 1642

Page 7

Misook Yu
July 9, 2003

Mary Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600